

CLASSIFICATION OF TRANSITIONAL DEVICES
AMENDMENTS ACT OF 1988

OCTOBER 6, 1988.—Ordered to be printed

Mr. KENNEDY, from the Committee on Labor and Human
Resources, submitted the following

REPORT

[To accompany S. 1808]

The Committee on Labor and Human Resources to which was referred the bill (S. 1808) to require the Secretary of Health and Human Services to determine the appropriate regulatory classification of the transitional devices of the Medical Device Amendments of 1976, and for other purposes, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill as amended do pass.

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I. SUMMARY OF THE BILL

The Classification of Transitional Devices Amendments Act of 1988, S. 1808, amends Section 520(1)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) to provide for the classification of so-called transitional medical devices. Transitional devices are those regulated as new drugs prior to the enactment of the Medical Device Amendments of 1976 (P.L. 94-295). At present, such devices

are automatically considered to be class III devices. This is the highest and most expensive of the three levels of device regulation. The definitions for classes I, II, and III are contained in Section 513(a)(1) of the Act.

The bill requires the Secretary of the Department of Health and Human Services to publish a notice stating, as to each type of transitional device, his initial conclusions as to whether the device should be retained as a class III device or be placed in class I or II. The notice will also require manufacturers of devices being considered for class I or II to submit reports of any adverse safety or effectiveness information known to them which has not previously been supplied to the Food and Drug Administration (FDA). Devices subject to pending petitions for reclassification will not be included in this notice.

Following a review of public comments on this notice, together with any information submitted by manufacturers, and after consultation with appropriate advisory panels, in accordance with the applicable portions of subsections (b) through (d) of the Section 513 of the Act, the Secretary is to publish a proposed regulation in the Federal Register for public comment. The proposed regulation is to assign to its appropriate regulatory class each of the transitional devices covered in the previously described notice.

After considering public comments on this proposal, the Secretary is to issue a final regulation classifying the devices in question. The bill contains a specific provision relating to nonhydrophilic plastic contact lenses to ensure that they will not be retained in class III unless they are found to meet the legal definition provided in Section 513(a)(1)(C)(ii) of the Act.

The bill provides a period of one year for completion of the above described activities. At the option of the Secretary, this period may be extended for up to an additional year, except that such extension will not apply to nonhydrophilic plastic contact lenses. The bill does not affect pending reclassification proceedings.

II. BACKGROUND AND NEED FOR LEGISLATION

The purposes of this bill is to resolve a long-standing problem regarding the medical device provisions of the Federal Food, Drug, and Cosmetic Act (the Act).¹ Specifically, the legislation requires the appropriate classification of the so-called "transitional devices" described in Section 520(l)(1) of the Act.

Under current law, all medical devices are classified into one of three classes, depending upon the degree to control needed to provide a reasonable assurance of safety and effectiveness. The Act provides a comprehensive procedure, involving public comment, for classifying these devices. Certain devices, those falling within the so-called "transitional provisions," were automatically assigned to class III, the most stringently regulated class; they have not gone through the regular classification process. There is no provision in the current law requiring the FDA to review the transitional devices and assign them to their appropriate regulatory classes. This has forced both the FDA and manufacturers of innocuous transi-

¹ 21 USC 301, et seq.

tional devices to expend substantial time and resources on inappropriate regulations.²

This situation has persisted for the twelve years since the enactment of the Medical Device Amendments of 1978 (P.L. 94-295), despite widespread recognition that many of these devices do not meet the statutory definition of a class III device.³ This definition is provided in Section 513(a)(1)(C) of the Act,⁴ and refers to devices which are intended for use in supporting human life or which present a potential unreasonable risk of illness or injury.

Unfortunately, it has proven impractical to assign these transitional devices to their appropriate regulatory classes under the present law.⁵ The situation was summarized by FDA Commissioner Young as follows:

[A] major PMA problem involves transitional devices By statute, these devices are automatically placed in class III instead of going through the classification process. Therefore, these devices . . . require approved premarket approval applications before they may be marketed If we are to amend this situation, it is difficult to envision a solution other than legislative change [W]e are uneasy about the current situation, where such transitional devices as sutures, contact lens, and lens solutions all must undergo premarket review and approval. (Speech to Health Industry Manufacturers Association, March 18, 1985; Emphasis added)

The continued regulation of some of these devices at the class III level has worked a hardship on various segments of the medical device industry, particularly the small manufacturers of contact lenses.⁶

² Class I devices generally involve the least expensive regulatory costs since compliance with the elaborate premarketing approval procedures is not required. These procedures can involve costs ranging from \$300,000 to \$1.5 million, or more, per device. In addition, it requires substantial time and resource commitment by FDA to review such premarket approval applications. Review time can range from 180 days to well over one year. Devices in class II, in theory, would have higher regulatory costs than class I devices since the former are required to comply with applicable performance standards. Since the FDA has developed no performance standards, the regulatory costs of marketing a class II device are equivalent to those associated with a class I device.

³ In a published interview, the Director of the FDA's Division of Ophthalmic Devices was asked why contact lenses continue to be regulated with the same restrictions as life-supporting drugs. He responded: "We are over-regulated, there's no question about it; the FDA support legislation that will down-classify devices. There are two such bills in Congress now [citing legislation introduced in the last Congress]. (Contact Lens Forum December 1986; page 33)."

⁴ 21 USC 360c(a)(1)(C).

⁵ This was confirmed by an FDA spokesman at the Committee's meeting held on July 14, 1988 to consider this measure. See exchange of correspondence between Senator Quayle and HHS Secretary Bowen (Appendix A).

⁶ In a report issued by OTA entitled "The Contact Lens Industry—Structure, Competition, and Public Policy" (OTA-HCS-31; December 1984), the following conclusions are stated:

Ideally, premarket approval would impose only those costs that are outweighed by the resulting benefits, but for soft and gas-permeable lenses this may not be the case. (page 51)

[C]lass III status . . . poses a formidable financial barrier for small firms. . . . The number of small producers has declined sharply, and most of the survivors have had to steadily reduce their output and employment levels. (page 52)

The Office of Technology Assessment (OTA) conducted an extensive study of the impact of the Medical Device Amendments of 1976 on the industry.⁷ The OTA concluded:

[M]ajor portions of the Medical Device Amendments have not been implemented by FDA and some may not be workable. As implemented so far, the regulatory process has posed the greatest problem for small manufacturers of contact lenses. (OTA Report Brief, October 1984)

Aside from the anticompetitive effects of such regulation, there is another equally serious problem. It requires a substantial commitment of FDA resources to process the large number of premarket approval applications submitted for transitional devices.⁸ This has diverted resources which might better be applied to more pressing public health concerns.

Far from protecting the welfare of the public, such unproductive use of scarce FDA resources reduces the agency manpower available for meeting pressing public health needs. In the introduction to the FDA's comprehensive "Plan for Action—Phase III" (May 1987), FDA Commissioner Young stated:

[H]usbanding of resources is essential to the agency's future in view of the challenges facing us, particularly the AIDS crisis and the need to enhance the approval of new drugs for life-threatening and serious illnesses.

An important part of the agency's action plan in fact relates to the transitional products which are the subject of this legislation. According to the FDA, such products account for 15 percent of the current medical device review workload. The FDA points out that:

Classification of these products into a more appropriate regulatory class based on estimates of risk will free up resources for those products which present greater risk to the public health, thereby reducing unnecessary regulation and enhancing necessary regulation. (page 9)

This legislation provides a badly needed mechanism for appropriate classification of the transitional devices. The intent of the legislation is that the Secretary will evaluate each of the transitional devices in the light of the detailed definitions provided in section 513(a) of the Act for class I, II, and III medical devices. The decision as to the appropriate classification for each of these devices is to be based on these definitions. If the device does not meet the class III definition, it should not be retained in class III. Proceedings conducted prior to the change in the law effectuated by this legislation will not furnish a basis for the findings required by the bill.

What is at stake is the rigor of market competition. Consumers of contact lenses may be less well off if small firms, which history shows to be especially vigorous competitors in contact lens development and pricing, are constrained, because of limited economic resources, from entering the market as effective rivals. (page 53)

⁷ "Federal Policies and the Medical Devices Industry" (OTA-H-230; October 1984).

⁸ FDA Commissioner Young has estimated that it requires 1,200 hours to review a premarket approval (PMA) submission (Speech to Health Industry Manufacturers Association, October 3, 1985). Studies done in the past indicate that almost half of the PMA's received by the FDA in a typical year relate to contact lens products (Tucker and Blozen, "PMA Applications for Post Amendment Devices: A Look at the Current Process," Medical Device and Diagnostics Industry, June 1983; p. 87).

A particularly pressing problem involves the so-called rigid gas permeable (RGP) contact lens. These make up a significant portion of the product review workload. As noted, their retention at the class III level has had a severe impact on small manufacturers of contact lenses.

Contact lenses may be defined in terms of their ability to absorb or attract water. The familiar soft lens is hydrophilic. That is, it absorbs a certain volume of water.⁹ Once the lens has been fully hydrated, a significant percentage of its weight will be made up of water. Nonhydrophilic (or hydrophobic) contact lenses, including the RGP lenses, do not absorb or attract significant amounts of water.¹⁰

The bill specifically states that nonhydrophilic plastic contact lenses are not to be retained in class III unless evidence is presented showing that they meet the legal definition, contained in Section 513(a)(1)(C)(ii) of the Act. Such evidence must be published in the Federal Register. Otherwise, these devices are to be assigned to either class I or class II. If the Secretary does not take action on nonhydrophilic plastic contact lenses within one year, they are to be assigned to class II.¹¹

The term "nonhydrophilic" as used in the bill refers to a plastic lens which, when fully hydrated, contains less than 10 percent water by weight. The FDA's ophthalmic advisory panel unanimously recommended reclassification of such lenses to class II.¹² The agency's own protracted attempt to reclassify foundered on what a reviewing court termed "the ironies effected by the statute,"¹³ and was terminated. In announcing its decision that it could not reclassify under the current law, FDA stated:

[R]eclassification of rigid gas permeable lenses would have resulted in increased competition, decreased costs, and an increase in employment and also would have allowed small contact lens firms to compete in the world market. (48 Federal Register 56798)

In correspondence directed to a Committee Member, HHS Secretary Bowen confirmed that the "general controls" applicable to all medical devices would permit the FDA to adequately regulate nonhydrophilic plastic contact lenses if they are reclassified (see Appendix A).

There are only about 20 transitional devices.¹⁴ In general, they do not present novel scientific questions and their appropriate clas-

⁹ The FDA has defined the soft, or hydrophilic, contact as one composed of "various polymer materials the main polymer molecules of which absorb or attract a certain volume (percentage) of water." (21 CFR 886.5925)

¹⁰ The FDA definition of the rigid gas permeable (nonhydrophilic) contact lens describes it as being composed of "various materials, such as cellulose acetate butyrate, polyacrylate-silicone, or silicone elastomers, whose main polymer molecules generally do not absorb or attract water." (21 CFR 886.5916).

¹¹ The Committee notes that the great majority of all medical devices today are regulated in either class I or class II. Class II contains such devices as metal hip joint replacement prosthesis (21 CFR 888.3350), the artificial eye (21 CFR 886.3200), eye sphere implants (21 CFR 886.3320), anesthesia machines (21 CFR 868.5160), and heart defibrillators (21 CFR 870.5300).

¹² See 46 Federal Register 57648 (November 24, 1981).

¹³ Contact Lens Manufacturers Association v. FDA, 766 F.2d 592, 603 (D.C.Cir. 1985).

¹⁴ These were identified in the Federal Register of December 16, 1977 (42 FR 63472), and include such diverse products as adhesive tape and injectable teflon.

sification should not involve great difficulty. Accordingly, the Committee expects that the Secretary will proceed in an expeditious manner to complete this long overdue process so that the redeployment of scarce agency resources to more productive work can commence as soon as possible.

Nevertheless, the legislation allows the Secretary to extend the classification period for up to an additional year by notice published in the Federal Register. Any such extension, however, will not affect the 90-day deadline for the issuance of the initial notice or the provision regarding nonhydrophilic plastic contact lenses.

The Committee is aware that a number of reclassification petitions regarding transitional devices are pending before FDA. Nothing in this legislation is intended to interfere with the timely completion of action under these petitions. The Committee expects the agency to complete action on such pending matters in an expeditious manner.

Finally, it is the Committee's intent that, to the maximum extent practicable, the Secretary shall provide an opportunity for interested persons to submit data and views to the advisory panels regarding the appropriate classification of the transitional devices.

APPENDIX A

U.S. SENATE,
Washington, DC, July 14, 1988.

Hon. OTIS R. BOWEN,
Secretary, Department of Health and Human Services, Washington, DC.

DEAR DOC: This morning the Labor and Human Resources Committee marked up S. 1808, the "Reclassification of Transitional Medical Devices Amendments of 1987." Under the substitute amendment (which was adopted) by Messrs. Kennedy and Hatch, any nonhydrophilic plastic contact lens is mandatorily reclassified as class II device if the Secretary has not made specified findings within one year of enactment.

During the discussion of this automatic reclassification provision, Mr. Hugh Cannon of the Food and Drug Administration asserted that such lenses are appropriately classified as class II and the only reason why FDA had not taken such reclassification action administratively was "a quirk in the law."

I would appreciate your written confirmation that this automatic reclassification procedure poses no threat to the health or safety of users of contact lenses. A prompt response would be appreciated so, that this exchange of correspondence could be included in the Committee report on the bill.

Sincerely,

DAN QUAYLE,
U.S. Senator.

THE SECRETARY OF HEALTH AND HUMAN SERVICES,
Washington, DC, September 29, 1988.

HON. EDWARD M. KENNEDY,
*Chairman, Committee on Labor and Human Resources,
U.S. Senate, Washington, DC.*

DEAR MR. CHAIRMAN: This is in response to your request for a report on S. 1808, a bill "To require the Secretary of Health and Human Services to determine the appropriate regulatory classification of the transitional devices of the Medical Device Amendments of 1976, and for other purposes."

In summary, we have no objection to this bill, S. 1808 would require the Secretary to initiate, for a small category of devices, classification proceedings based on specific and detailed scientific evidence than the law now requires for the classification or reclassification of all other devices. However, the risk of harm to consumers should be negligible, because of the types of devices that would be subject to these proceedings, and because of the proposed legislation's built-in safeguards that would permit the Food and Drug Administration (FDA) to refrain from lowering the classification of these devices if that agency found it inappropriate to do so. The authority for "down-classification" of transitional devices in this manner is acceptable because any devices that may be reclassified could possibly be overregulated under present law. Moreover, should these classification proceedings lead to less regulation of some medical devices, FDA resources could be shifted to other activities with higher public health payoff.

The Medical Device Amendments of 1976 (the Amendments) amended the Federal Food, Drug, and Cosmetic (FFD&C) Act to establish a three-tiered system for the regulation of medical devices, under which devices were to be classified in accordance with their level of risk. Class I (general controls) applies to all devices and represents the minimum level of control. Class I controls include establishment registration and device listing, premarket notification, and adherence to good manufacturing practices among other statutory requirements. Class II (performance standards) requires the development of standards for devices to provide reasonable assurance of their safety and effectiveness. Class III (premarket approval) is the most stringent level of control and requires the submission of data, including clinical data, to establish the safety and effectiveness of devices prior to marketing.

Before enactment of the Amendments, certain devices were treated by FDA as new drugs and were subject to premarket approval based upon full reports of investigations to show that they were safe and effective. The Amendments designated these and other devices that were declared by FDA to be new drugs, and devices substantially equivalent to them, as "transitional devices" and classified them into class III. The Amendments provide for reclassification of transitional devices into class I or II based upon a showing that the device meets specific statutory criteria that define the class into which the device is to be reclassified. Depending upon the circumstances, this process can be quite demanding in terms of data, cost and time.

S. 1808 would require the Secretary to initiate classification proceedings for all transitional devices and substantially equivalent devices. Under S. 1808, the classification proceedings would consist of a review by FDA of postmarketing surveillance data supplied by manufacturers and consultation with existing advisory panels. The Secretary would initiate the process by identifying in a notice those transitional devices that would be reviewed for classification into class I or II and those devices that would remain in class III. For nonhydrophilic plastic contact lenses, all of the above actions would have to occur within one year after enactment of S. 1808 or the Secretary would be required to issue a notice placing these devices in class II.

This bill reflects concerns expressed in recent years that some medical devices have been subject to overregulation and that this situation is not easily correctable because of constraints on the use of certain proprietary data in FDA's files. S. 1808 could make it easier for FDA to "down-classify" some devices that may be inappropriately, and therefore wastefully, regulated as class III devices.

S. 1808 would establish a different standard of scientific review for transitional devices based on less data than are currently required for the classification or reclassification of all other medical devices. Currently, medical devices are classified or reclassified based on "valid scientific evidence" as required by the FFD&C Act and defined in regulations. This standard would not apply to transitional devices. We generally do not favor the establishment of dual standards in the FFD&C Act (one standard for transitionals, another for all other devices). We also have misgivings about the precedent of inserting product-specific provisions into the FFD&C Act.

On the other hand, the product-specific provisions for transitional devices embodied in S. 1808 are at least consistent with the original statutory scheme of the Medical Device Amendments of 1976, which afford FDA a substantial amount of discretion in deciding which devices should be placed in class III as transitional devices. The Amendments simply placed into class III those devices that FDA had previously treated as, or declared to be "new drugs." FDA had taken these actions for approximately 20 categories of medical devices (out of 1700 categories of devices) that it had deemed to warrant the type of premarket reviews established for new drugs in order to ensure safety and effectiveness. S. 1808 would now mandate that, over a decade later, FDA reconsider its prior classification decisions for transitional devices in a manner that would be similarly discretionary and more feasible than current law permits.

As noted above, for one particular type of transitional device, nonhydrophilic plastic contact lenses, S. 1808 would require these devices to be classified into class II unless FDA affirmatively retained them in class III. As a general rule, we do not favor provisions of this type, because we could not rule out the possibility that the operation of an automatic procedure in lieu of a scientific determination would have untoward public health consequences. In this case, however, the provision in S. 1808 that would permit FDA to withhold certain transitional devices from the classification proceedings would provide a significant safeguard. Additionally, based

on information from FDA's adverse reaction reporting networks and other information known to that agency, we would not expect that nonhydrophilic plastic contact lenses that are produced consistent with good manufacturing practice requirements, with materials that have been on the market for many years, and with acceptable optical qualities, would present a risk of harm to consumers. The "general controls" in the FFD&C Act would permit FDA to determine whether lenses meet this data by the manufacturer, including clinical data if necessary, to show comparability (i.e., that one lens was "substantially equivalent" to another). We believe, incidentally, that the same conclusions would apply to rigid gas permeable and soft daily wear contact lenses as well as to nonhydrophilic plastic lenses. It is not clear why that portion of S. 1808 that specifically addresses contact lenses includes one type but not the other two.

Moreover, because transitional devices, primarily contact lenses, account for approximately half of all applications for premarket approval received by FDA, this bill does offer the potential for freeing some agency resources for the review of applications involving newly emerging technologies and devices that pose significant potential public health risks, thus permitting faster product reviews for devices with potentially greater public health benefits.

For the foregoing reasons, we would not object to enactment of S. 1808.

The Office of Management and Budget has advised that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

OTIS R. BOWEN, M.D.,
Secretary.

III. TEXT OF THE BILL AS REPORTED

[S. 1808, 100th Congress, 2d Session]

A BILL to require the Secretary of Health and Human Services to determine the appropriate regulatory classification of the transitional devices of the Medical Device Amendments of 1976, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, [That this Act may be cited as the "Reclassification of Transitional Devices Amendments of 1987".

[REQUIREMENT TO DETERMINE THE APPROPRIATE REGULATORY CLASSIFICATION OF THE TRANSITIONAL DEVICES OF THE MEDICAL DEVICE AMENDMENTS OF 1976

[SEC. 2. (a) Section 520(1)(2) of the Federal Food, Drug, and Cosmetic Act is amended by inserting "(A)" before "The manufacturer or importer" and by adding at the end thereof the following new subparagraph:

["(B)(i) Within the ninety-day period beginning on the date of enactment of the Reclassification of Transitional Devices Amendments of 1987, the Secretary shall initiate a proceeding to reclassify all devices placed in class III pursuant to paragraph (1) of this

subsection. Within twelve months after such date of enactment, the Secretary shall, by order, reclassify each such device into class I or II or determine that the device should remain in class III. The proceeding conducted under this clause shall be limited to a determination, based on valid scientific evidence, of whether each such device meets the criteria for inclusion in class III set forth in subclauses (I) and (II) of section 513(a)(1)(C)(ii).

["(ii) The Secretary shall not continue the classification of a device in class III unless the Secretary finds that the device meets the criteria set forth in subclauses (I) and (II) of section 513(a)(1)(C)(ii).

["(iii) A device described in paragraph (1) which has not been the subject of an order issued pursuant to clause (i) of this subparagraph and which is in class III shall be reclassified in class II. A reclassification under this clause shall take effect one year after date of enactment of the Reclassification of Transitional Devices Amendments of 1987.".

["(b) Section 520(l)(1) of such Act is amended by striking out "paragraph (2)" and inserting in lieu thereof "paragraph (2)(A)"."]

SECTION 1. SHORT TITLE.

This Act may be cited as the "Classification of Transitional Devices Amendments Act of 1988".

SEC. 2. REQUIREMENT TO DETERMINE THE APPROPRIATE REGULATORY CLASSIFICATION OF THE TRANSITIONAL DEVICES OF THE MEDICAL DEVICE AMENDMENTS OF 1976.

(a) *IN GENERAL.*—Section 520(l)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(l)(2)) is amended—

(1) by inserting "(A)" after the paragraph designation; and

(2) by adding at the end thereof the following new subparagraph:

"(B)(i) Not later than 90 days after the date of enactment of the Classification of Transitional Devices Amendments Act of 1988, the Secretary shall publish a notice in the Federal Register with respect to devices that are subject to regulation pursuant to this subsection. The notice shall state whether each device shall remain in class III or be reviewed for classification into class I or II. The notice shall also require the manufacturer of a device that the Secretary intends to classify into class I or II to submit to the Secretary a description of and citation to any adverse safety and effectiveness information not submitted under section 519. The Secretary may require a manufacturer to submit the adverse safety and effectiveness information for which a description and citation were submitted to the Secretary.

"(ii) After the issuance of the notice under clause (i), and following consultation with appropriate advisory panels in accordance with subsections (b) through (d) of section 513, but before the expiration of 1 year after the date of enactment of the Classification of Transitional Devices Amendments Act of 1988, the Secretary shall publish a proposed regulation in the Federal Register classifying each such device into class I or II, or providing that each such device shall remain in class III. The data furnished by manufacturers, pursuant to clause (i), in combination with the advice and recommendation of appropriate advisory panels, shall, for the advice

and recommendation of appropriate advisory panels, shall, for purposes of this Act, serve as a basis for satisfying the criteria set forth in subclauses (I) or (II) of section 513(a)(1)(C)(ii), and shall serve as a basis for the proposed regulation required under this subparagraph.

"(iii) Following a review of comments received on the proposed regulation issued pursuant to clause (ii), and before the expiration of the 1-year period referred to in clause (ii), the Secretary shall promulgate a final regulation prescribing the classification of all devices presently regulated under this subsection. No regulation issued under this subparagraph requiring a device to remain in class III or classifying such a device in class I or II may take effect before the expiration of 90 days from the date of its publication in the Federal Register.

"(iv) The Secretary may by notice in the Federal Register extend the 1-year period prescribed by clauses (ii) and (iii) for a device for an additional period not to exceed 1 year.

"(v) Notwithstanding any other provision of this subsection, the Secretary shall not retain any nonhydrophilic plastic contact lens in class III unless the Secretary finds that it meets the criteria set forth in subclauses (I) or (II) of section 513(a)(1)(C)(ii). Any such finding, and the grounds therefore, shall be published in the Federal Register. If during the 1-year period beginning on the date of enactment of the Classification of Transitional Devices Amendments Act of 1988 the Secretary has not made the finding and issued the notice required by this clause, the Secretary shall issue an order placing such lens in class II.

"(vi) Actions taken under this subparagraph shall not interfere with any pending reclassification action. Any device on which a reclassification action is pending shall not be included in the list published under clause (i)."

(b) CONFORMING AMENDMENT.—Section 520(l)(1) of such Act is amended by striking out "paragraph (2)" and inserting in lieu thereof "paragraph (2)(A)".

IV. COMMITTEE VIEWS

This legislation provides a badly needed mechanism for appropriate classification of the transitional devices. The intent of the legislation is that the Secretary will evaluate each of the transitional devices in the light of the detailed definitions provided in section 513(a) of the Act for class I, II, and III medical devices. The decision as to the appropriate classification for each of these devices is to be based on these definitions. If the device does not meet the class III definition, it should not be retained in class III. Proceedings conducted prior to the change in the law effectuated by this legislation will not furnish a basis for the findings required by the bill.

A particularly pressing problem involves the so-called rigid gas permeable (RGP) contact lens. These make up a significant portion of the product review workload, and their retention at the class III level has had a severe impact on small manufacturers of contact lenses.

Contact lenses may be defined in terms of their ability to absorb or attract water. The familiar soft lens is hydrophilic. That is, it

absorbs a certain volume of water.⁹ Once the lens has been fully hydrated, a significant percentage of its weight will be made up of water. Nonhydrophilic (or hydrophobic) contact lenses, including the RGP lenses, do not absorb or attract significant amounts of water.¹⁰

The bill specifically states that nonhydrophilic plastic contact lenses are not to be retained in class III unless evidence is presented showing that they meet the legal definition, contained in Section 513(a)(1)(C)(ii) of the Act. Such evidence must be published in the Federal Register. Otherwise, these devices are to be assigned to either class I or class II. If the Secretary does not take action on nonhydrophilic plastic contact lenses within one year, they are to be assigned to class II.¹¹

The term "nonhydrophilic" as used in the bill refers to a plastic lens (including RGP) which, when fully hydrated, contains less than 10 percent water by weight. The FDA's ophthalmic advisory panel unanimously recommended reclassification of such lenses to class II.¹² The agency's own protracted attempt to reclassify foundered on what a reviewing court termed "the ironies effected by the statute,"¹³ and was terminated. In announcing its decision that it could not reclassify under the current law, FDA stated:

[R]eclassification of rigid gas permeable lenses would have resulted in increased competition, decreased costs, and an increase in employment and also would have allowed small contact lens firms to compete in the world market." (48 Federal Register 56798)

In correspondence directed to a Committee Member, HHS Secretary Bowen confirmed that the "general controls" applicable to all medical devices would permit the FDA to adequately regulate nonhydrophilic plastic contact lenses if they are reclassified (see Appendix A).

There are only about 20 transitional devices.¹⁴ In general, they do not present novel scientific questions and their appropriate classification should not involve great difficulty. Accordingly, the Committee expects that the Secretary will proceed in an expeditious manner to complete this long overdue process so that the redeployment of scarce agency resources to more productive work can commence as soon as possible.

Nevertheless, the legislation allows the Secretary to extend the classification period for up to an additional year by notice published in the Federal Register. Any such extension, however, will

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¹⁰ The FDA definition of the rigid gas permeable (nonhydrophilic) contact lens describes it as being composed of "various materials, such as cellulose acetate butyrate, polyacrylate-silicone, or silicone elastomers, whose main polymer molecules generally do not absorb or attract water." (21 CFR 886.5916)

¹¹ The Committee notes that the great majority of all medical devices today are regulated in either class I or class II. Class II contains such devices as metal hip joint replacement prosthesis (21 CFR 888.3350), the artificial eye (21 CFR 886.3200), eye sphere implants (21 CFR 886.3320), anesthesia machines (21 CFR 868.5160), and heart defibrillators (21 CFR 870.5300).

¹² See 46 Federal Register 57648 (November 24, 1981).

¹³ Contact Lens Manufacturers Association v. FDA, 766 F.2d 592, 603 (D.C. Cir. 1985).

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not effect the 90 day deadline for the issuance of the initial notice or the provision regarding nonhydrophilic plastic contact lenses.

The Committee is aware that a number of reclassification petitions regarding transitional devices are pending before FDA. Nothing in this legislation is intended to interfere with the timely completion of action under these petitions. The Committee expects the agency to complete action on such pending matters in an expeditious manner.

Finally, it is the Committee's intent that, to the maximum extent practicable, the Secretary shall provide an opportunity for interested persons to submit data and views to the panels regarding the appropriate classification of the transitional devices.

V. COMMITTEE ACTION

S. 1808 was considered by the Committee on July 14, 1988, and reported favorably with an amendment in the nature of a substitute by unanimous vote.

VI. COST ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, August 10, 1988.

Hon. EDWARD M. KENNEDY,
*Chairman, Committee on Labor and Human Resources,
U.S. Senate, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the attached cost estimate for S. 1808, the Classification of Transitional Devices Amendments Act of 1988, as ordered reported by the Senate Committee on Labor and Human Resources on July 14, 1988.

If you wish further details on this estimate, we will be pleased to provide them.

Sincerely,

JAMES L. BLUM,
Acting Director.

Attachment.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

1. Bill number: S. 1808
2. Bill title: Classification of Transitional Devices Act of 1988.
3. Bill status: As ordered reported by the Senate Committee on Labor and Human Resources on July 14, 1988.
4. Bill purpose: To require the Secretary of Health and Human Services (HHS) to determine the appropriate regulatory classification of the transitional devices of the Medical Device Amendments of 1976.
5. Estimated cost to the Federal Government:

[By fiscal years, in millions of dollars]

	1989	1990	1991	1992	1993
Transitional Devices:					
Estimated Authorization Level	1	1	—	—	—
Estimated Outlays	1	1	—	—	—

The costs of this bill fall within budget function 550.

Basis of Estimate: CBO estimated the authorization for this program and assumes that all authorizations are fully appropriated at the beginning of each fiscal year. Outlays are estimated using spendout rates computed by CBO on the basis of recent program data.

S. 1808 would provide for the possible reclassification of certain transitional medical devices. In addition, the bill would require the Food and Drug Administration (FDA) to publish regulations in the Federal Register for the possible reclassification of these devices. Transitional medical devices are devices regulated as drugs prior to 1976 but reclassified later as medical devices. About twenty medical devices fall into this category. Based on information provided by the Food and Drug Administration, we estimate that this activity would cost about \$1 million in each fiscal year, 1989 and 1990.

6. Estimated cost to State and local government: None.

7. Estimate comparison: None.

8. Previous CBO estimate: None.

9. Estimate prepared by: Lori Housman.

10. Estimate approved by: C.G. Nuckols (for James L. Blum, Assistant Director for Budget Analysis).

VII. REGULATORY IMPACT STATEMENT

The Committee has determined that there will be minimal or no increase in the regulatory burden of paperwork as a direct result of this bill. In fact, the Committee believes that enactment of S. 1808 may result in a reduction in the regulatory burden of paperwork.

VIII. SECTION-BY-SECTION ANALYSIS

S. 1808, "Classification of Transitional Device Amendments Act of 1988" As reported by the Committee on Labor and Human Resources.

Section 1 of the bill cites the Act as the "Classification of Transitional Device Amendments Act of 1988."

Section 2(a) of the bill amends Section 520(1)(2) of the Federal Food, Drug and Cosmetic Act.

Clause (i) requires the Secretary of Health and Human Services to publish in the Federal Register a notice within 90 days listing the transitional devices to be evaluated by the FDA for reassignment to classes I or II.

The notice will state, for each such device, the proposed classification assignment and will require manufacturers of such devices to submit reports on adverse safety and effectiveness experience not previously reported under section 519 of the present law.

Clause (ii) directs the Secretary, in consultation with appropriate advisory panels, to evaluate those transitional devices being considered for reclassification in accordance with the applicable provisions in sections 513(b) through (d) of the present law. Such evaluations must take place and the proposed class assignments must be published for public commentary within one year of the passage of the Classification of Transitional Devices Act of 1988. Safety and effectiveness information supplied by manufacturers and the criteria set forth in section 513(a)(1)(C)(ii) will serve as the basis for the proposed regulation.

Clause (iii) directs the Secretary to review public comments received in response to the proposal issued pursuant to clause (ii), and publish final classification regulations, within one year of the passage of this legislation. The new regulations will be effective no less than 90 days after the proposal is published.

Clause (iv) makes an allowance for the Secretary to publish a notice in the Federal Register if a time extension is needed to evaluate transitional devices, but this extension is not to exceed one year.

Clause (v) states that nonhydrophilic plastic contact lenses are not to be retained in class III unless evidence is presented showing that they meet the legal definition contained in Section 513(a)(1)(C)(ii) of the present law. Such evidence must be published in the Federal Register. Otherwise, these devices are to be assigned to either class I or class II. If the Secretary has not completed action on nonhydrophilic plastic contact lenses within one year, they are to be assigned to class II.

Clause (vi) clarifies the sort of transitional device eligible for consideration under the bill. Transitional devices for which reclassification petitions are pending will not be considered under this legislation.

Section 2(b) is a conforming amendment.

IX. CHANGES IN EXISTING LAW

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute of the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

* * * * *

CHAPTER V—DRUGS AND DEVICES

SUBCHAPTER A—DRUGS AND DEVICES

ADULTERATED DRUGS AND DEVICES

* * * * *

GENERAL PROVISIONS RESPECTING CONTROL OF DEVICES INTENDED FOR
HUMAN USE

General Rule

SEC. 520. (a-k) * * *

Transitional Provisions for Devices Considered as New Drugs or
Antibiotic Drugs

(1)(1) Any device intended for human use—

(A) for which on the date of enactment of the Medical Device Amendments of 1976 (hereinafter in this subsection referred to as the "enactment date") an approval of an application submitted under section 505(b) was in effect;

(B) for which such an application was filed on or before the enactment date and with respect to which application no order of approval or refusing to approve had been issued on such date under subsection (c) or (d) of such section;

(C) for which on the enactment date an exemption under subsection (i) of such section was in effect;

(D) which is within a type of device described in subparagraph (A), (B), or (C) and is substantially equivalent to another device within that type;

(E) which the Secretary in notice published in the Federal Register before the enactment date has declared to be a new drug subject to section 505; or

(F) with respect to which on the enactment date an action is pending in a United States court under section 302, 303, or 304 for an alleged violation of a provision of section 301 which enforces a requirement of section 505 or for an alleged violation of section 505(a),

is classified in class III unless the Secretary in response to a petition submitted under [paragraph (2)] *paragraph (2)(A)* has classified such device in class I or II.

(2)(A) The manufacturer or importer of a device classified under paragraph (1) may petition the Secretary (in such form and manner as he shall prescribe) for the issuance of an order classifying the device in class I or class II. Within thirty days of the filing of such a petition, the Secretary shall notify the petitioner of any deficiencies in the petition which prevent the Secretary from making a decision on the petition. Except as provided in paragraph (3)(D)(ii), within one hundred and eighty days after the filing of a petition under this paragraph and after affording the petitioner an opportunity for an informal hearing, the Secretary shall, after consultation with the appropriate panel under section 513, by order either deny the petition or order the classification, in accordance with the criteria prescribed by section 513(a)(1)(A) or 513(a)(1)(B), or the device in class I or class II.

(B)(i) Not later than 90 days later after the date of enactment of the Classification of Transitional Devices Amendments Act of 1988, the Secretary shall publish a notice in the Federal Register with respect to devices that are subject to regulation pursuant to this subsection. The notice shall state whether each device shall remain in class III or be reviewed for classification into class I or II. The

notice shall also require the manufacturer of a device that the Secretary intends to classify into class I or II to submit to the Secretary a description of and citation to any adverse safety and effectiveness information not submitted under section 519. The Secretary may require a manufacturer the adverse safety and effectiveness information for which a description and citation were submitted to the Secretary.

(ii) After the issuance of the notice under clause (i), and following consultation with appropriate advisory panels in accordance with subsections (b) through (d) of section 513, but before the expiration of 1 year after the date or enactment of the Classification of Transitional Devices Amendments Act of 1988, the Secretary shall publish a proposed regulation in the Federal Register classifying each such device into class I or II, or providing that each such device shall remain in class III. The data furnished by manufacturers, pursuant to clause (i), in combination with the advice and recommendation of appropriate advisory panels, shall, for the advice and recommendation of appropriate advisory panels, shall, for purposes of this Act, serve as a basis for satisfying the criteria set forth in subclauses (I) and (II) of section 513(a)(1)(C)(ii), and shall serve as a basis for the proposed regulation required under this subparagraph.

(iii) Following a review of comments received on the proposed regulation issued pursuant to clause (ii), and before the expiration of the 1-year period referred to in clause (ii), the Secretary shall promulgate a final regulation prescribing the classification of all devices presently regulated under this subsection. No regulation issued under this subparagraph requiring a device to remain in class III or classifying such a device in class I or II may take effect before the expiration of 90 days from the date of its publication in the Federal Register.

(iv) The Secretary may by notice in the Federal Register extend the 1-year period prescribed by clauses (ii) and (iii) for a device for an additional period not to exceed 1 year.

(v) Notwithstanding any other provision of this subsection, the Secretary shall not retain any nonhydrophilic plastic contact lens in class III unless the Secretary finds that it meets the criteria set forth in subclauses (I) and (II) of section 513(a)(1)(C)(ii). Any such finding, and the grounds therefore, shall be published in the Federal Register. If during the 1-year period beginning on the date of enactment of the Classification of Transitional Devices Amendments Act of 1988 the Secretary has not made the finding and issued the notice required by this clause, the Secretary shall issue an order placing such lens in class II.

(vi) Actions taken under this subparagraph shall not interfere with any pending reclassification action. Any device on which a reclassification action is pending shall not be included in the list published under clause (i).

(3)(A) In the case of a device which is described in paragraph (1)(A) and which is in class III—

(i) such device shall on the enactment date be considered a device with an approved application under section 515, and

(ii) the requirements applicable to such device before the enactment date under section 505 shall continue to apply to such

device until changed by the Secretary as authorized by this Act.

(B) In the case of a device which is described in paragraph (1)(B) and which is in class III, an application for such device shall be considered as having been filed under section 515 on the enactment date. The period in which the Secretary shall act on such application in accordance with section 515(d)(1) shall be one hundred and eighty days from the enactment date (or such greater period as the Secretary and the applicant may agree upon after the Secretary has made the finding required by section 515(d)(1)(B)(i)) less the number of days in the period beginning on the date an application for such device was filed under section 505 and ending on the enactment date. After the expiration of such period such device is required, unless exempt under subsection (g), to have in effect an approved application under section 515.

(C) A device which is described in paragraph (1)(C) and which is in class III shall be considered a new drug until the expiration of the ninety-day period beginning on the date of the promulgation of regulations under subsection (g) of this section. After the expiration of such period such device is required, unless exempt under subsection (g), to have in effect an approved application under section 515.

(D)(i) Except as provided in clauses (ii) and (iii), a device which is described in subparagraph (D), (E), or (F) of paragraph (1) and which is in class III is required, unless exempt under subsection (g) of this section, to have on and after sixty days after the enactment date in effect an approved application under section 515.

(ii) If—

(I) a petition is filed under paragraph (2) for a device described in subparagraph (D), (E), or (F) of paragraph (1), or

(II) an application for premarket approval is filed under section 515 for such a device,

within the sixty-day period beginning on the enactment date (or within such greater period as the Secretary, after making the finding required under section 515(d)(1)(B), and the petitioner or applicant may agree upon), the Secretary shall act on such petition or applicant in accordance with paragraph (2) or section 515 except that the period within which the Secretary must act on the petition or application shall be within the one hundred and twenty-day period beginning on the date the petition or application is filed. If such a petition or application is filed within such sixty-day (or greater) period, clause (i) of this subparagraph shall not apply to such device before the expiration of such one hundred and twenty-day period, or if such petition is denied or such application is denied approval, before the date of such denial, whichever occurs first.

(iii) In the case of a device which is described in subparagraph (E) of paragraph (1), which the Secretary in a notice published in the Federal Register after March 31, 1976, declared to be a new drug subject to subsection 505, and which is in class III—

(I) the device shall, after eighteen months after the enactment date, have in effect an approved application under section 515 unless exempt under subsection (g) of this section, and

(II) the Secretary may, during the period beginning one hundred and eighty days after the enactment date and ending eighteen months after such date, restrict the use of the device to investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of such device, and to investigational use in accordance with the requirements applicable under regulations under subsection (g) of this section to investigational use of devices granted an exemption under such subsection.

If the requirements under subsection (g) of this section are made applicable to the investigational use of such a device, they shall be made applicable in such a manner that the device shall be made reasonably available to physicians meeting appropriate qualifications prescribed by the Secretary.

(4) Any device intended for human use which on the enactment date was subject to the requirements of section 507 shall be subject to such requirements as follows:

(A) In the case of such a device which is classified into class I, such requirements shall apply to such device until the effective date of the regulation classifying the device into such class.

(B) In the case of such a device which is classified into class II, such requirements shall apply to such device until the effective date of a performance standard applicable to the device under section 514.

(C) In the case of such a device which is classified into class III, such requirements shall apply to such device until the date on which the device is required to have in effect an approved application under section 515.

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